ZEISS Guides Manufacturers to FDA Validation of Coordinate Measurement Machines

ZEISS Medical Industry Solutions

Quality Assurance for the Highest Medical Standards

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Seeing beyond

FDA Guidelines and Validation Methods

Medical device manufacturing customers often ask: “If I buy a coordinate measuring machine (CMM), does the measuring software come validated by the standards of the Food and Drug Administration (FDA)? And if not, what do I need to do to validate it?”

The key issue in validation is to preserve the integrity of a reliable and dependable measurement process. But what many customers do not understand is that CMM equipment and software cannot be validated by the CMM supplier – it’s ultimately the customer’s application that needs to be considered for FDA compliance.

ZEISS Industrial Quality Solutions, in cooperation with many FDA-compliant users, have established guidelines and validation methods to comply with FDA standards. ZEISS is now providing support to validate any CMMs and the entire inspection process.

Meeting Industry Standards for Validation

Validation is a required component of medical device quality assurance. But medical device manufactures new to CMMs aren’t always sure how to achieve FDA compliance.

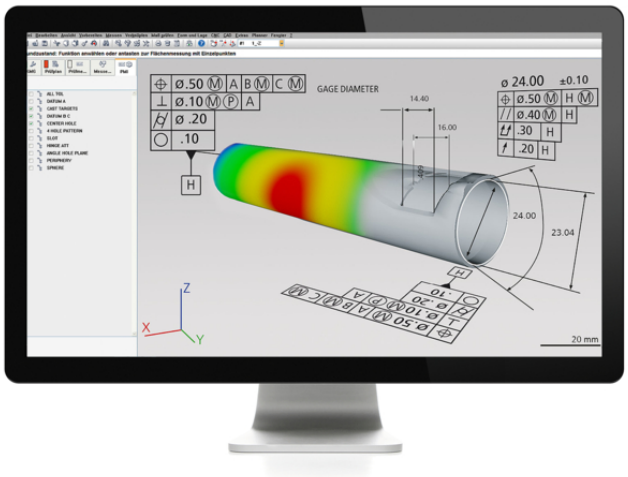
These businesses often ask the CMM supplier to provide FDA solutions and validation guidance to meet the industry standards, including, 21 CFR Part 11 and 21 CFR 820.

21 CFR Part 11 & 820

To support the FDA, Current Good Manufacturing Practices (CGMP) requirements are set forth in quality system regulations, says the Electronic Code of Federal Regulations (eCFR). These CGMP requirements include 21 CFR Part 11 and 21 CFR Part 820:

- 21 CFR Part 11 considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.
- 21 CFR Part 820 ensures that all medical devices created and developed within the US market are safe, follow satisfactory quality processes at all stages of development.

Performing process validation ensures that the process output is predictable and predetermined. In order to accomplish this, the medical device manufacture must have a clear list of requirements and specifications (URS) to test the installation and operation of both the CMM system and the inspection process. This test is also known as the Installation Qualification/Operational Qualification, or IQ/OQ.



Understanding Metrology Software Methodology

Challenges in Validating Measurement Systems and Software

CFR Part 11 and CFR Part 820 were not written specifically for CMMs and metrology software. Consequently, not all regulations may apply to these systems.

For example, although CMMs create electronic records, a CMM does not modify, maintain or transmit electronic records. Therefore, these aspects of the regulations may not apply.

Also, a validated closed system in production does not typically have a need for manual signatures in the process. Without manual signatures required in the process, regulating that an electronic signature be trustworthy, reliable and generally equivalent to handwritten signatures is irrelevant. Knowing what regulations apply is not always clear.

But the biggest question from the medical industry is what aspects of metrology software needs to be validated and how is this done.

FDA provides regulation on this topic with §820.70 Production and process controls for Automated processes: “When computers or automated data processing systems are used as part of production or the quality system, the [medical device] manufacturer shall validate computer software for its intended use according to an established protocol.”

The challenge is that the metrology software is a programming language. The programs written are executed in production and represent the intended use of the software. It is these inspection programs and not the metrology software that must be validated to established protocols.

The other challenge to validating the metrology software is that there are no established protocols or industry standards for evaluation and reporting all the dimensional characteristics used to inspect medical devices. The National Metrology Institute of Germany (PTB) and National Institute of Standards and Technology (NIST) both evaluate fitting algorithms and calculate geometric features to expected values. These evaluations do add value to the validation of the metrology software, however, the PTB and NIST evaluations are far from the software’s intended use.

And when it comes to validating the entire CMM, there is not a clear separation between validating the CMM system and the inspection process.

The CMM System includes all aspects of:

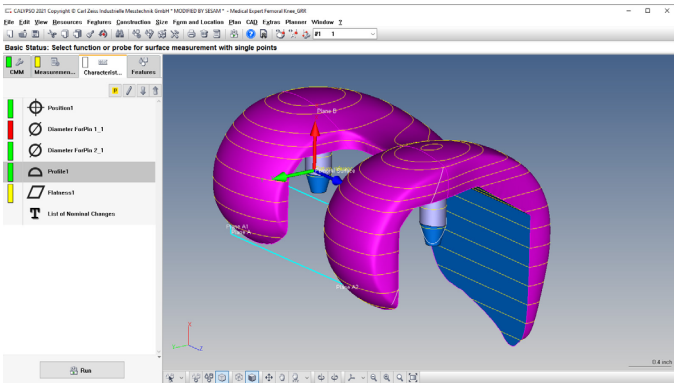
- Machine
- Software
- Environment
- IT security
- Training

The CMM system needs to be validated prior to handing over to the applications team for programming and defining the inspection process.

The inspection Process for each part defines which dimensions are to be measured on the finished part or a given operation. The process includes:

- Programming
- Fixturing
- Tooling
- Identifying the part
- Validating measurement results

A well-defined URS and IO/OQ plan are required for both the CMM system and the inspection process. And the CMM system and inspection process need to be validated by the medical device manufacture. The CMM and metrology software provider should be providing guidance for both validation processes.



Helping Medical Device Manufacturers with FDA Regulations

ZEISS Solution to Validate Measurement Plans

ZEISS is helping medical device manufactures understand how the FDA regulations apply to CMM equipment and inspection processes and are providing guidelines to validation.

This compliance starts with the evaluation of the CMM provider, which is clarified by FDA regulation on §820.50(a)(1): “Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements.”

ZEISS provides guidelines on these quality requirements of a CMM provider and how they should be evaluated.

Next, ZEISS can help a medical device manufacture define URS design and planning documents and the IQ/OQ validation documents for both the CMM system and the inspection process. The URS documents are fundamentally required prior to implementing an FDA solution and are the base for validation.

As well, ZEISS also provides the required documentation to establish that metrology software is developed and maintained to ISO 9001 quality standards and testing is conducted by national institutes. More importantly, ZEISS provides guidelines on validating the measurement programs and the complete inspection process. ZEISS’s Measurement Plan Design Process describes how to create a robust, valid measurement plan and ensure that inspection results are valid and correct.

ZEISS to Educate Customers on Validation

Through webinars, lectures and formal training, ZEISS is leading the industry in providing guidelines on validating CMM systems and inspection processes.

For live online training, two classes are available.

- **Part 1, 1-Day.**
  "Introduction to CMM Validation for FDA Compliance" is a class appropriate for quality managers to learn the fundamentals of validating CMM systems and inspection processes.
- **Part 2, 3-Day**
  "Guidelines to ZEISS Systems and CALYPSO Validation" is ZEISS-specific and appropriate for CMM programmers to learn the validation details of ZEISS CMMs and CALYPSO metrology software.

Conclusion

ZEISS Industrial Quality Solutions has the experience, knowledge and credibility to clarify methods in metrology validation. ZEISS is using this to cover new ground and have become the industry leader in FDA solutions.

Contact us to schedule a demo with our ZEISS experts.

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